

Declaration of Antony Fields
U.S.S.N. 10/081,569

EXHIBIT 5 OF FIELDS DECLARATION

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Emphasys Endobronchial Valve System

Instructions for Use

CAUTION: Investigational device. Limited by United States law to investigational use. Not for sale in the United States.

Single Use Only
Sterilized by ethylene oxide gas
Nonpyrogenic
Do not resterilize

Description

The Emphasys Endobronchial Valve (EBV) is an endobronchial prosthesis that is intended to control airflow. The device consists of a one-way, duckbill valve that is contained within a self-expanding retainer. It is implanted in the target bronchus using a flexible delivery catheter that is guided to the targeted bronchus by a guidewire. The Valve is designed to be a permanent implant.



Retainer
Seals
Face of first seal
Valve

Emphasys Endobronchial Valve

Measured Bronchial Diameter	Recommended EBV		Recommended Delivery Catheter
	Size	Length	
4.0 – 5.5 mm	4.0 mm	10 mm	4.0--S
5.0 – 7.0 mm	5.0 mm	10 mm	5.0--M
6.5 – 8.5 mm	6.5 mm	10 mm	6.5--L

Required Equipment

- Adult flexible bronchoscope (working channel ≥ 2.2 mm, outside diameter ≤ 6 mm)
- Olympus bendable measuring device
- Water based sterile lubricant (such as K-Y® Jelly, Johnson & Johnson, Arlington, Texas)
- EndoTracheal tube (ID ≥ 9 mm)
- Bronchoscope Adaptor (such as Fiberoptic Bronchoscope Swivel Adaptor, SIMS Portex Inc., Keene, NH)

Note: a smaller endotracheal tube may be used in conjunction with a smaller bronchoscope. Verify that the bronchoscope and Delivery Catheter shaft will fit within the selected endotracheal tube and bronchoscope adaptor.

System Components

- Emphasys Endobronchial Valve (EBV) (various sizes)
- Emphasys Delivery Catheter
- Emphasys Loading System
- Guidewire (180 cm x 0.035" diameter)

Indications for Use

The Emphasys EBV is an implantable bronchial valve intended for use in patients with heterogenous emphysema who meet the eligibility criteria outlined in the study protocol.

Contraindications

The Emphasys EBV is contraindicated in patients that do not meet the eligibility criteria outlined in the study protocol.

Warnings and Precautions

Read all labels and instructions prior to use. Use of the Emphasys Delivery Catheter and Emphasys EBV should only be performed by or under the supervision of physicians trained in the placement of Emphasys Endobronchial Valves.

Warning: Iatrogenic injury from the Delivery Catheter may occur if excessive forces are applied during use.

Caution: Airway occlusion may be impaired if the EBV seal extends proximally beyond the carina of the target bronchus.

Warning: Avoid any aggressive insertion of the guidewire as excessive insertion forces may result in airway perforation.

Complications

Potential complications are outlined in the study protocol.

Recommended Procedure

1. Measure Bronchus Diameter

Insert a flexible bronchoscope (working channel ≥ 2.2 mm) through an endotracheal tube or rigid bronchoscope, and locate the target bronchus. Advance the bronchoscope to the carina of the target bronchus. An Olympus bendable measuring device (M2-1/2/3/4) may be used to measure the bronchus diameter. Advance the measuring device through the working channel of the bronchoscope, bend the tip using the actuator on the handle, and measure the diameter of the targeted bronchus. The Emphasys EBV should be selected as follows:

Caution: Under-sizing or over-sizing of the EBV may impair the ability of the EBV to completely occlude the airway.

Caution: Confirm free movement within the bronchoscope adaptor with the bronchoscope alongside the Delivery Catheter. If movement in the adaptor appears too constrained, change to a larger adaptor or smaller bronchoscope.

2. Guidewire Placement

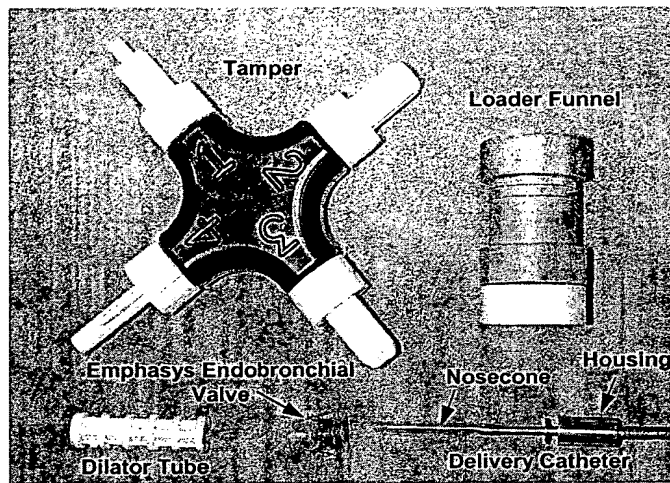
Advance the 180 cm, 0.035" Guidewire through the working channel of the flexible bronchoscope. Advance the distal tip of the Guidewire into the target bronchus. Continue to advance the distal tip of the Guidewire at least 2 cm beyond the EBV placement target. Remove the bronchoscope from the patient entirely, leaving the Guidewire in place. Fluoroscopy may be used at this step to ensure that the Guidewire is not displaced while removing the bronchoscope.

Warning: Avoid any aggressive insertion of the Guidewire as excessive insertion forces may result in a perforation.

3. Emphasys Endobronchial Valve (EBV) Loading

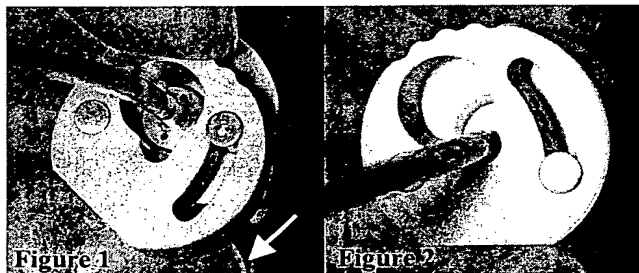
Select the appropriate size loader for the Delivery Catheter. Size matching can be verified by the color on the system components and labels.

Size	4.0	5.0	6.5
Color	White	Blue	Green



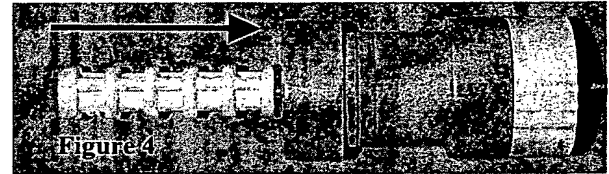
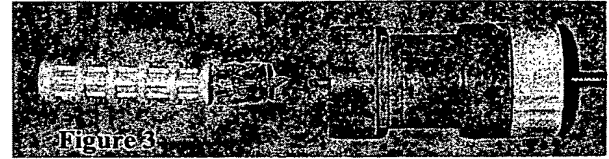
Loader System

Rotate the housing lock on the Loader Funnel to the side and insert the nosecone and housing of the Delivery Catheter into the Loader Funnel (see Figure 1). Release the housing lock and verify that the housing is secured in the Loader Funnel (see Figure 2).



Apply sterile, water-based lubricant to the EBV (especially the face of the first seal), the Loading Tube,

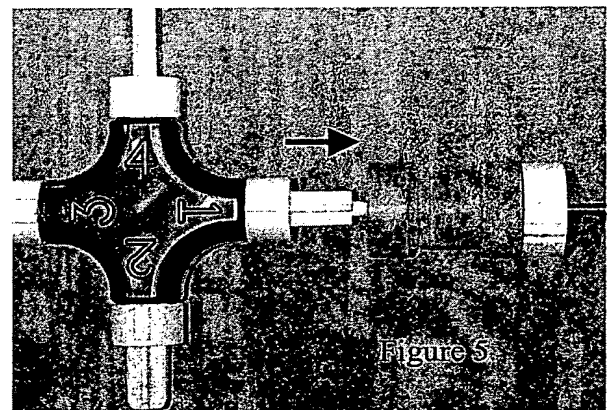
the Loader Funnel and to the Delivery Catheter nosecone. Slide the Dilator Tube through the EBV from the distal to proximal direction (see Figure 3). Slide the Dilator Tube over the Delivery Catheter nosecone. Slide the EBV off the Dilator Tube and onto the Delivery Catheter nosecone (see Figure 4). Remove the Dilator Tube.

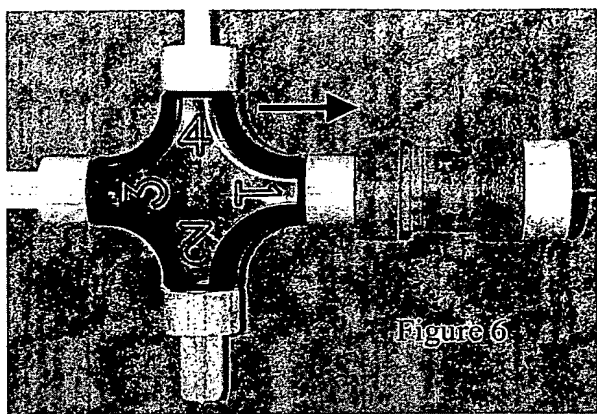


Next, use the Tamper to push the EBV into the Loader Funnel. Note that the Tamper is numbered to correspond with the tamping sequence. Using the number 1 Tamper, slide the Tamper over the nosecone and push the EBV into the Funnel. Gently advance the Tamper until it is in contact with the face of the Funnel (see Figures 5-6). Repeat with Tampers 2-4.

Warning: Verify that the EBV is loaded with the valve pointed towards the proximal end of the Delivery Catheter. A valve placed in the reverse direction may result in hyperinflation of the distal lung.

Caution: Ensure that adequate lubrication is applied to the EBV (especially the face of the first seal), the Loader Funnel and Loading Tube. Inadequate lubrication may result in high loading forces, failure to deploy the EBV, and / or damage to the EBV.





Caution: Use only moderate force to push the EBV into the housing of the Delivery Catheter. If resistance is met while loading the EBV, do not force the Tamper. Advance the catheter handle to free the EBV and discard. Excessive loading forces may result in damage to the EBV and / or deployment difficulty.

Once all four Tampers have been used to push the valve into the catheter, remove the loaded system from the Funnel by rotating the housing lock and releasing the Delivery Catheter shaft. Tighten the thumbscrew lock on the handle to ensure that the EBV is not prematurely deployed during placement of the Delivery Catheter. Verify that the protruding portion of the EBV is uniform about the housing and that none of the retainer prongs are bent back or exposed at the tip of the housing (see Figure below for appearance of correctly loaded EBV).



Caution: If EBV is not to be deployed immediately, place delivery catheter housing in sterile saline bath until it is needed.

4. Emphasys Delivery Catheter Placement

While keeping the Guidewire fixed relative to the patient, backload the Guidewire into the Delivery Catheter. Advance the Delivery Catheter into the trachea. Advance a flexible bronchoscope behind the proximal edge of the Delivery Catheter housing. A combination of wire manipulation and rotation of the Delivery Catheter can be used to facilitate tracking around acute angles and bifurcations. The flexible bronchoscope can be used to provide direct visualization during the positioning of the EBV. Before deployment of the EBV, visually confirm

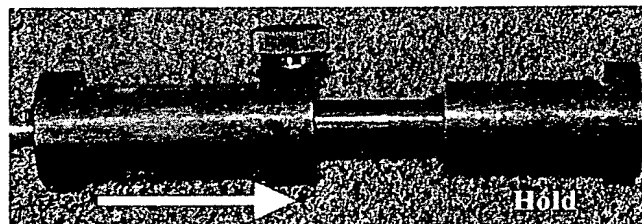
that the device is positioned so that the proximal edge of the housing (EBV container) is distal to or flush with the carina of the target bronchus.

Caution: The Emphasys EBV is designed for placement in bronchi at least 10 mm in length. Placement of the EBV in undersized bronchi may compromise Valve function.

Caution: Airway occlusion may be impaired if the EBV seal extends proximally beyond the carina of the target bronchus.

5. Emphasys Endobronchial Valve (EBV) Deployment

Loosen the thumbscrew lock on the handle to allow deployment. While fixing the proximal portion of the Delivery Catheter handle relative to the patient (e.g. relative to an endotracheal tube), pull back on the distal portion of the handle to deploy the device effectively sliding the housing off the stationary EBV (see Figure below). Once fully deployed, the Delivery Catheter and Guidewire are removed.



The inner valve leaflets should appear the same as in their preloaded condition. If the valve leaflets are inverted, they can be flipped back by advancing a biopsy tool or small balloon catheter past then retracting the device back through the valve. The deployed EBV should be seated distal to the carina of the target bronchus. At a minimum, the two distal seals should be seated within the bronchus and the entire circumference of the large seal should contact the bronchial wall. Remove and discard the EBV if the seals are not engaged.

Caution: The Emphasys Delivery Catheter may be loaded and used for deployment a maximum of four (4) times on a single patient before discarding. The loader may be used for all loadings for a single patient before discarding.

Removal may be accomplished by using rat-tooth graspers to grip one of the cutouts located in the metal sleeve surrounding the inner duckbill valve and carefully pulling to retract the valve. An alternate technique is to advance the rat-tooth graspers (via the bronchoscope working channel) through the center of the valve, opening the graspers and pulling gently to retract the EBV device.

Warning: Do not attempt to remove a large EBV through an ET tube smaller than 9.0 mm.

Caution: If an ET tube smaller than 9 mm is used, a 6.5 mm EBV may become lodged and impede airflow to patient if withdrawn into the ET tube. To reduce the risk of airway blockage, do not attempt to pull a removed 6.5 mm valve back through the ET tube. Instead, when the removed valve is retracted to the point of being just distal to the ET tube, extubate the patient and simultaneously extract the EBV while monitoring via bronchoscopy. Reintubate patient if necessary.

Storage

Store the packaged Emphasys EBV and accessories at room temperature. Do not expose to extreme heat or moisture.

Patents pending

100-0322-01

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